Section 5: 510k) Summary

The Summary of Safety and Effectiveness on the ALT Laser, Model AVI HPLL-12 reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Avicenna Laser Technology, Inc. Bruce Coren, DVM, MS. 9822 East Washington Street, Suite 6 Chagrin Falls, Ohio 44023 JUL 2 8 2009
Telephone **Facsimile**	(561) 722 – 1153 (561) 820 – 9646
Date	April 24, 2009
Name	ALT Laser, Model AVI HPLL-12
Classification	Infrared Lamp, 21 CFR 890.5500
Predicate:	ALT Laser, Model VTR75, K031612 market clearance date December 11, 2003
Description	The system will produce a 980nm infrared and a 650 nm red visible laser light in overlapping patterns. The two types of light will be mixed such that the visible 650 nm light becomes a reasonable indicator of the invisible infrared 980nm light. The 650 nm visible aiming laser light will be sensed and if the light is absent, it will lock out the infrared 980nm light and alert the operator.
Intended Use	ALT Laser, Model AVI HPLL-12 is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of the muscle tissue.
Contraindications	• Do not apply infrared light to abdominal or lumbosacral points in pregnant females. • Do not apply infrared light to the epiphyseal lines in children. • Do not apply infrared light to the thorax or over the pacemaker itself in patients with pacemakers. • Do not apply infrared light over the thyroid gland, ovaries and testicles. • Do not apply infrared light to patients who are taking drugs that have heat or light sensitive contraindications, such as but not limited to certain types of steroids
Warning	• Do not use in the presence of flammable solvents or anesthetics. • Never look directly into the laser light source or at scattered laser light from any reflective surfaces. Never sight down the beam into the source. • Direct eye contact with the output beam from the laser will cause serious damage and possible blindness. • Avoid direct exposure to the laser light. The intensity of the beam can easily cause flesh burns or ignite clothing. • Never look directly into the beam or at a specular reflection even while wearing protective eyewear.

510(k) SUMMARY, continue

The Summary of Safety and Effectiveness on the ALT Laser, Model AVI HPLL-12 reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Caution	• Always wear laser safety eyewear, which is optically dense at the wavelength of operation. • Limit access to the laser to qualified users who are familiar with laser safety practices and who are aware of the dangers involved. • As a precaution against accidental exposure to the output beam or its reflection, those using the system should wear laser safety glasses as required by the wavelength being generated. • Use the laser in an enclosed room. Laser light will remain collimated over long distances and therefore prevents a potential hazard if not confined. • Post warning signs in the area of the laser beam to alert those present. • Advise all those using the laser of these precautions. It is good practice to operate the laser in a room with controlled and restricted access. • Always wear laser safety eyewear, which is optically dense at the wavelength of operation. • Use safety interlocks to restrict access to laser areas and prevent unauthorized use of the laser. • Post warning signs for class IV laser products.
Substantial Equivalency Information	The light at infrared wavelengths is therapeutic in nature and although the output of infrared energy varies between devices this difference only impacts the amount of time to attain the therapeutic thermal effect of the infrared energy. Therefore, the operational differences and output between the predicate device ALT Laser VTR 75 and ALT Laser, Model AVI HPLL-12 does not present a significant effect in the therapeutic outcome.
Technological Characteristics	The intended use and technological characteristic of the two devices do not vary significantly. The safety and effectiveness of the Avicenna Laser Technology, Inc.'s ALT Laser, Model AVI HPLL-12 infrared device is comparable to that of the Avicenna's ALT Laser Model VTR 75 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2009

Avicenna Laser Technology, Inc.
% Bruce R. Coren, DVM, MS
President
9822 East Washington Street, Suite 6
Chagrin Falls, Ohio 44023

Re: K091285
Trade/Device Name: ALT Laser, Model AVI HPLL-12
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: June 19, 2009
Received: July 6, 2009

Dear Dr. Coren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800).638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indication for Use Summary

510(k) Number (if known): K091285

Device Name: ALT Laser, Model AVI HPLL-12

Indications For Use:

ALT Laser, Model AVI HPLL-12 is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of the muscle tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091285

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)